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A Novel Intervention to Simultaneously Address the Dual Pathologies of Breathing Disorders During Sleep and Undiagnosed Attention Deficit Hyperactivity Disorder in School-Aged Children Ages 5–12

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Abstract

Purpose: To evaluate the improvement of ADHD related symptoms in school-aged children ages 5 to 12 in treatment with a monobloc appliance (MOA) for Sleep Disordered Breathing (SDB). **Methods:** A retrospective review of questionnaire scores of ADHD symptoms from school-aged children being treated with a MOA for SDB. Data was obtained from parent survey questionnaires of 40 school-aged children in three dental offices in treatment with an MOA for SDB showing symptoms of ADHD yet to be confirmed with a formal diagnosis between 2019 and 2021. ADHD symptom scores were ascertained by a parent survey questionnaire completed at the initial visit before MOA treatment, and 2 to 6 months, and 7+ months during MOA treatment. **Results:** At the 7+ month endpoint, 17 of the 28 (61%) children ages 5 to 12 saw at least a 1-point drop in the sum of their questionnaire scores indicating an improvement in ADHD symptoms after initiating treatment with an MOA. Although there was a reduction of the overall average symptom score from the initial visit to 2 to 6 months ($M = 4.06$, $SD \pm 1.55$), a statistically significant improvement in ADHD symptoms occurred at the 7+ month endpoint ($M = 15.29$, $SD \pm 4.50$) during MOA treatment. **Conclusions:** Treatment with an MOA may be highly effective in addressing the dual pathologies of SDB and ADHD in school-age children ages 5 to 12. *(J. of Att. Dis. XXXX; XX(X) XX-XX)*

Keywords

attention deficit hyperactivity disorder, sleep disordered breathing, obstructive sleep apnea, monobloc oral appliance

Introduction

ADHD is the most common neurological disorder connected to significant deficits that expand among a variety of neurocognitive functioning and sleep pathologies (Ahmadi et al., 2014; Pievsky & McGrath, 2018). Affecting approximately 9.4% of children and 2.5% of adults from childhood into adulthood, 25% to 50% of children diagnosed with ADHD have a breathing disorder and sleep related issue (Centers for Disease Control and Prevention, n.d.a; Kessler et al., 2006; Youssef et al., 2011). Early publications to examine the links between sleep and ADHD occurred in 1957 with the treatment guidelines as far back as the 1970s, specifically the rigorous review of stimulant drugs (Laufer & Denhoff, 1957; Wolraich et al., 2019). Over time, the reviews discovered a correlation between the pathophysiology of interrupted sleep and inattention from irregular arousals and cyclical changes in the brains of children, three times more likely in males than in females (Barkley, 1990; Grünwald & Schlarb, 2017; Owens, 2005).

The Diagnostic and Statistical Manual of Mental Disorders (DSM), 5th ed., defines ADHD in two symptom domains of 18 symptoms as "a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or developmental level and that negatively impacts directly on social and economic/occupational activities" (American Psychiatric Association, 2013). There is

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no test to diagnose ADHD but requires the presence of at least 6 of the 18 symptoms by the age of 12 in two settings with unmistakable evidence of disrupted activities of daily living for proper diagnosis (American Psychiatric Association, 2013; Cabral et al., 2020). However, sleep deprivation patterns and disturbances associated with inattentiveness are not considered criteria for an ADHD diagnosis under the DSM guidelines (American Psychiatric Association, 2013; Faraone et al., 2021; Grohol, 2013).

FDA-approved, age-appropriate pharmacotherapy frequently used in the evidenced-based treatment of ADHD is dependent on the clinical presentation and physician preference (Drechsler et al., 2020). Certain pharmacotherapy options may take up to 16 weeks for a response in the reduction of symptoms with the risk of recurring ADHD after an initial period of remission (Connolly et al., 2015). Categorically, medications used for ADHD may cause sleep problems and daytime sleepiness potentially enhancing remission of ADHD symptoms occurring in 60% of children after the initial remission (Sibley et al., 2022; Stein et al., 2012; Turgay, 2007). While concomitant modalities such as Cognitive Behavioral Therapy (CBT) and educational services from a 504 or Individual Education Plan (IEP) may provide relief or assistance, they do not cure ADHD (Center for Disease Control and Prevention, n.d.b; Pan et al., 2019). A 504 and IEP are formal plans schools develop to remove learning barriers for children with learning disabilities or deficiencies so they can access the curriculum. Unfortunately, children's behavioral patterns are often misdiagnosed as hyperactive and inattentive then subsequently medicated when they are simply sleep deprived or exhibiting a form a normal developmental pattern (Center for Disease Control and Prevention, n.d.b; Slobodin & Davidovitch, 2022).

Sleep related breathing disorders causing sleep disruption may be a cause of behavioral issues in ADHD. If left untreated, they can evolve into obstructive sleep apnea (OSA) which is one of the top three sleep related diagnosis affecting up to 33% of patients diagnosed with or without symptoms of ADHD (Owens, 2005; Tsukada et al., 2018; Urbano et al., 2021; Youssef et al., 2011). The prevalence of breathing disorders at sleep impacts 15% of children due to variations in the upper airway, while 90% will go undiagnosed as adults (Gokdemir et al., 2021). The relationship between SDB and ADHD has been proposed yet remains controversial in a scenario of which came first (Gokdemir et al., 2021; Slobodin & Davidovitch, 2022; Tsukada et al., 2018; Urbano et al., 2021; Wu et al., 2017). While adults may feel fatigued from sleep deprivation, it's not uncommon for sleep-deprived children to become hyperactive; another reason is that a child may be misdiagnosed with ADHD instead of sleep apnea (Javaheri & Javaheri, 2020; Knight & Dimitriou, 2019; Tan et al., 2013). Grünwald and Schlarb (2017) verified the relationship between subtypes, symptoms of ADHD, and sleep in connection with quality of life in children. Presentation of sleep disturbances intrinsically associated with undiagnosed ADHD symptoms suggest the need for an evaluation of sleep quality and patterns during treatment discussions and considerations (Ben-Dor Cohen et al., 2021; Gokdemir et al., 2021; Tsukada et al., 2018; Urbano et al., 2021; Wu et al., 2017).

In an extensive literature review, the findings suggest ADHD symptoms related to breathing disorders at sleep find short term efficacy and improvement with adenotonsillectomy (Amiri et al., 2015). The success in the amelioration of ADHD symptoms using other treatment options such as an MOA in the pediatric population experiencing breathing disorders in children ages 5 to 12 has not been adequately evaluated (Amiri et al., 2015; Escobar et al., 2021). Escobar et al. (2021) hypothesized ADHD symptoms can be reduced by treating OSA and breathing disorders with Rapid Maxillary Expansion (RME) or a Mandibular Advancement Device (MAD). In a previous study, the effectiveness of early intervention with a MOA in reducing symptoms of breathing disorders at sleep in children with dentofacial anomalies ages 5 to 12 was completed and published (Davidson et al., 2023). This retrospective review is the first to examine the reduction or resolve of ADHD symptoms using an MOA in school-aged children with a known SDB diagnosis found in the effectiveness study (Davidson et al., 2023). It is hypothesized that oral appliance therapy can resolve breathing problems and reduce undiagnosed ADHD symptoms.

Methods

WCG IRB's IRB Affairs Department reviewed the study under the Common Rule and applicable guidance and determined the study is exempt with a waiver of consent under 45 CFR § 46.104(d)(4). Consent for treatment was obtained and on file with the providers at each center. This was a retrospective review of symptom rating scores from an adjunct sleep disorder breathing study which were retrieved from a post hoc data mining of a large database. Children were referred to a dental provider for evaluation of SBD; and receiving an MOA as a treatment option between 2019 and 2021. As part of the assessment, a set of 28 questions on the Sleep, Breathing, & Habit Questionnaire were answered with a rating score of frequency by the parent or guardian at each visit. The multi-center, sample of 40 questionnaire scores from children ages 5 to 12 examined five commonly reported symptoms of ADHD. Inclusion criteria identified boys and girls between the ages of 5 and 12 in treatment with an MOA for SDB exhibiting symptoms of ADHD without a confirmed diagnosis. Exclusion criteria were children below the age of 5 or older than 12, involvement in an Investigational Review Board (IRB) clinical trial, patients with known genetic conditions affecting the airway such as

Figure 1. Examples of MOAs used in the study: vStarter for Kids is used in patients who typically have not had their first molars erupt yet. vStarter used in patients who typically have their first molars either partially erupting or fully erupted. Vivos Grow (VG) is used primarily in mixed dentition patients and come in 10 different sizes. Vivos Guide (VW) specifically designed for permanent dentition to control second permanent molars. (Used with permission from Vivos Therapeutics, Inc.).

Down syndrome, children with a confirmed ADHD diagnosis, and subjects not in MOA oral appliance treatment. Sleep, Breathing & Habit Questionnaire questions used to collect the symptoms is provided in the Appendix in the Supplement. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational studies.

A sample of five commonly reported ADHD symptoms were subjectively measured using an approved Sleep, Breathing & Habit Tool completed by a parent or guardian during dental visits; the initial visit, the first follow-up visit between 2 and 6 months, and the follow-up visit after 7+ months, for a total of three endpoints. For each record, the following information was collected and recorded as a nominal value in the data set: gender (coded as 1 for female and 2 for male), age, length of MOA treatment, and individual scores of 0 to 3 for short attention span, trouble focusing, difficulty listening, struggles in math, and struggles in reading. We categorized the scores for ADHD symptoms as 0 for no occurrence, 1 for rarely occurred, 2 for occurred two to three times per week, and 3 for occurred five to seven times per week. For the purpose of the review, ADHD symptoms were considered resolved at a frequency score of 0 or 1. Data was coded on a rating scale according to the frequency score of symptoms to create the baseline and endpoint metrics when evaluating group comparison tests. The groups were composed as follows: Sample group 1 (SG1) compared the initial sample scores of children who had follow-up visits between 2 and 6 months and completed the 2 to 6 month questionnaire. Sample group 2 (SG2) compared the initial sample scores of children who had follow-up visits after 7+ month and completed the 7+ questionnaire.

The MOA (Vivos Therapeutics, Denver, CO) identified in this study is an FDA-registered, Class I orthodontic appliance and tooth positioner with a fused upper and lower tray forming a single unit for patients 4 years of age and older usually worn at night. The concept of the MOA is to promote a lip seal, reposition and retrain the tongue to sit more up and forward in the mouth, enhance nasal breathing, and improve sleep. Contraindication of MOAs in children include non-nasal breathing patients, patients with restricted oral tissues, and those with a severe gag reflex issue. Graphics of the MOA used in treatment are shown in Figure 1.

Statistical Analysis

IBM SPSS Statistics software (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY; IDM Corp.) and R studio were used to perform the statistical analysis and features and summaries of the dataset. The statistical analysis used a paired *t*-test to compare the frequency of behaviors related to ADHD reported between three endpoints: baseline, 2 and 6 months (SG1) and 7+ months (SG2) to determine if there was a statistically significant improvement of reported symptoms with an MOA. The calculated *t*-statistic was then compared to the critical *t*-value at a significance level of $p < .05$.

To determine the improvement of ADHD symptoms in children with SDB, the following null hypothesis was tested. Test 1: count of symptoms with score of 2 or 3 at initial endpoint = or ≠ count of symptoms with score of 2 or 3 at final endpoint. Test 2: mean of average score for initial results = or ≠ mean of average score for final results

Prior to using pairwise statistical *t*-test for mean comparison, the following assumptions were considered and met:

1. Mean of both samples (initial and final results) follow a normal distribution. This was tested using the Shapiro-Wilk normality test. However, in cases where the sample size is large enough, samples follow a normal distribution through the central limit theorem.

Table 1. Participant Characteristics and Sample frequency in a Study of School-Age Children with SDB and ADHD behaviors and symptoms (n = 40).

Years	Frequency	Percent	Percent of males	Percent of females
5	8	20	50.0	50.0
6	5	12.5	80.0	14.0
7	3	7.5	33.0	67.0
8	15	37.5	33.0	67.0
9	4	10	25.0	75.0
10	3	7.5	33.0	67.0
11	1	2.5	-	100.0
12	1	2.5	100.0	-

2. Data are independently and identically distributed. In the case of pairwise data, data points must match up and be equally paired.

In the cases where data was non-parametric, the Wilcoxon signed rank test was used vs the standard *t*-tests.

Results

Demographics and Main Clinical Features

In total, 40 Sleep, Breathing, & Habit Questionnaires of school-aged children from three dental offices were reviewed. The mean age of children who had completed questionnaires at three endpoints was 7.5 years, (±1.79). In the group, there were 22 females (55%) and 18 males (45%) (Table 1). Table 2 shows the baseline frequencies of ADHD behaviors and symptoms reported from the study sample at the beginning of analysis.

Evaluation of SG1

SG1 data was found to be normally distributed through the central limit theorem. As such, the findings of statistical test for mean comparison conducted to evaluate ADHD behaviors and symptoms occurring often (2–7 times per week) using a count as well as the samples average score of all ADHD behaviors and symptoms did not indicate significance in the reduction. The overall frequency count of ADHD behaviors and symptoms identified as occurring 2 to 7 times a week (scores 2 and 3) from the initial visit (M = 1.5, SD ± 1.57) to the second endpoint (M = 1.45, SD ± 1.57) showed an average reduction in their count of 0.03 (95% CI [−0.39, 0.46]; p = .88). Likewise, results with SG1 did not show significance in the reduction of the overall average behavior frequency score from the initial visit (M = 1.00, SD ± 0.79) to the second endpoint (M = 0.88, SD ± 0.80), with an average reduction in their overall average frequency score of 0.13 (95% CI [−0.08219, 0.3332]; p = .227). Patients in SG1 had an average treatment time of 4.06 (SD ± 1.56) months Table 3.

Evaluation of SG2

Given that the data were not normally distributed for SG2, the nonparametric Wilcoxon signed rank test was used. Similarly, to SG1 evaluations, the results showed significance in both areas of testing with a reduction of the overall frequency count of ADHD behavior and symptoms occurring 2 to 7 times a week (scores 2 and 3) from the initial visit ($Md\,n$ = 1.0, IQR = 3.0) to the final endpoint (Mdn = 0.0, IQR = 2.0), with an average reduction in their frequency count of 0.54 (p = .01), and an average treatment time of 15.29 (SD ± 4.50) months. Likewise, results with SG2 saw a statistically significant reduction of the overall average behavior and symptom score from the initial visit (Mdn = 0.9, IQR = 1.3) to the final endpoint (Mdn = 0.6, IQR = 1.0), with an average reduction in their overall average frequency score of 0.3 ($p < .01$) Table 4.

Discussion

In this retrospective review of parent-reporting questionnaires of school-aged children ages 5 to 12, showing behavior and symptoms of undiagnosed ADHD during treatment with an MOA for SDB, improvement or resolve of all behaviors and symptoms were seen over time. The statistical testing observed differences that are unlikely to be produced by chance.

Impulsivity and hyperactivity are seen more often by the untrained eye and reported as ADHD rather than sleep deprivation. By reducing the amount of impulsively or hyperactivity seen in sleep deprivation and disturbances with SDB, the sleep-wake cycle can improve in MOA treatment addressing the two pathologies simultaneously. The study found "Hyperactivity" resolved or markedly improved within 2 to 6 months. Likewise, "Difficulty Listening," a symptom reported at the 7+ month endpoint than any other symptom, showed the most improvement among the reported behaviors. This symptom is common in children with or without hearing loss, and further confirms the need to consider behavioral or sleep related breathing disorders when evaluating impairment in executive functions of the brain.

Additional factors associated with ADHD symptoms and sleep related breathing disorders is adenoid hypertrophy found in children 4 to 5 years old, and tonsillar hypertrophy found in children 6 to 11 years old (Amiri et al., 2015). The concomitant comorbidities found between ADHD and OSA are found in 30% of this age group and is increasing (Davidson et al., 2023; National Institute of Mental Health, n.d.). A link to sleep disturbances and ADHD may also be found in medications with more than 64% of children on

Table 2. Baseline Behaviors and Symptoms of the Study Sample With SDB and Self-Reported ADHD Symptoms at the Initial Visit (*n* = 40).

	No occurrence (%)	Occurs rarely (%)	Occurs 2–4 times per week (%)	Occurs 5–7 times per week (%)
Short attention	46.2	23.1	17.9	12.8
Difficulty listening	23.1	23.1	23.1	30.7
Hyperactive	42.5	25	15	17.5
Math struggle	59.5	18.9	10.8	10.8
Reading struggle	75.7	8.1	10.8	5.4

Table 3. Improvement of ADHD Behaviors and Symptoms With MOA in School-Aged Children Ages 5 to 12 With a Diagnosis With SDB at 2 to 6 Months (*n* = 32).

Improvement	No occurrence (%)	Occurs rarely (%)	Occurs 2–4 times per week (%)	Occurs 5–7 times per week (%)
Short attention	54.8	12.9	25.8	6.5
Difficulty listening	34.4	21.9	34.4	9.4
Hyperactive	53.1	25.0	18.8	3.1
Math struggle	51.6	12.9	25.8	9.7
Reading struggle	70.0	13.3	10.0	6.7

Table 4. Improvement of ADHD Behaviors and Symptoms With MOA in School-Aged Children Ages 5 to 12 With a Diagnosis With SDB at 7 + Months (*n* = 28).

Improvement	No occurrence (%)	Occurs rarely (%)	Occurs 2–4 times per week (%)	Occurs 5–7 times per week (%)
Short attention	51.7	24.1	17.2	6.9
Difficulty listening	41.4	31.0	17.2	10.3
Hyperactive	75.9	17.2	3.4	3.4
Math struggle	53.6	25.0	21.4	0
Reading struggle	71.4	17.9	10.7	0

medication for ADHD: ages 2–5: 18%, ages 6–11: 69%, and ages 12–17: 62% (Bonuck et al., 2011; Center for Disease Control and Prevention, n.d.a; National Institute of Mental Health, n.d.).

This is the first study to describe the relationship between early intervention with an MOA and improvement in dual pathologies of SDB and ADHD symptoms. These findings suggested the importance of assessing sleep and breathing patterns in children before the diagnosis and pharmacotherapy treatment for ADHD in children between 5 and 8 years old. Comparable to the prevalence of OSA among boys with the mean age of diagnosis for ADHD at 7 years found in the literature (Bonuck et al., 2011; Davidson et al., 2023; National Institute of Mental Health, n.d.), the mean age for this review was 7.50 years with 10% more girls than boys.

This review also has implications for preventive medicine in sleep and mental health disorders as 95% of adults diagnosed with ADHD recall their symptoms starting before the age of 12 (Markowitz et al., 2020). If the research findings are parallel to the literature review and earlier research supporting the link between ADHD and SDB, it warrants the message to urge teachers, clinicians, and school administrators to consider sleep problems and breathing disorders when a child manifests a behavioral and attention problem (Center for Disease Control and Prevention, n.d.b; Gokdemir et al., 2021; Markowitz et al., 2020). It could be SDB that is aggravating the symptoms of ADHD. This is especially important in the case of misdiagnosed ADHD and the risk of prescribing stimulants that could cause further sleep problems.

One aspect to consider in the increase of ADHD diagnoses and SDB, is the growth and development of the human skull over time (Spencer et al., 1998). Children with high nasal resistance found in SDB are predisposed to snoring that can further result in adult OSA (Ngiam & Cistulli, 2015). The compensatory action of mouth breathing in OSA creates an imbalance in the skeletal formation and muscular function of the face resulting in malocclusions, retrognathia, and postural issues (Jones & Bhatia, 1994; Ngiam & Cistulli, 2015; Spencer et al., 1998; Valera et al., 2003). The increasing number of conversations on nasal function, nasal resistance, SDB, and craniofacial development in early childhood have created a market of oral appliances and tooth positioners to be used in this age group between the ages of 5 and 12 (Escobar et al., 2021; Huang & Guilleminault, 2012).

This study presented with limitations. First, the qualitative format of gathering information from the parent's perspective is useful for analyzing behaviors; however, there may be an underlying emotional tone to their response on the questionnaire. One participant did not provide a frequency score for two variables at the 7+ endpoint. Second, limited data and information were retrieved from home and assumed in the school setting based on teacher reports. The next study should include the National Institute for Children's Health Quality (NICHQ) Vanderbilt Assessment Scale to validate behavioral changes in the classroom for the 6 to 12-year-old age group (Gokdemir et al., 2021). The NICHQ Vanderbilt Assessment Scale is used by healthcare professionals to diagnosis ADHD in children ages 6 to 12 years by rating the symptoms based on age appropriateness. Forth, sleep studies to confirm an OSA diagnosis was not noted by the providers. Although the history and physical are important for sleep disorder assessments, a polysomnography (PSG) test confirming OSA may not be part of the data because they are expensive, time consuming, and used inconsistently in children. Fifth, the data was retrospective listing five of the six necessary symptoms at minimum for an ADHD diagnosis suggesting the necessity of a prospective study in the near future. A study control group and denial of treatment for one group may be deemed as unethical research in pediatric subjects. Also, the data presented more females than males which may impact the numbers of improvement as girls are less likely to exhibit as much hyperactivity as boys. Sixth, socioeconomic variables, ADHD diagnosis, and ADHD medication profile were not reported by the parent during the dental visit. Lastly, details lack the breakdown of each device in use as each child and the severity of SDB will vary as they move through the MOA program.

Conclusions

In this study we reviewed how the MOA mediated the improvement of ADHD behaviors and symptoms for younger kids as most kids are diagnosed with ADHD at 6 to 12 years old.

Undiagnosed ADHD behaviors and symptoms among school-aged children in MOA treatment for sleep and breathing disorders improved in 4.22 months and were reported as resolved or rarely occurred in 15 months among 17 of 28 kids (61%). The results emphasize the need to assess sleeping patterns in children before a confirmed diagnosis of ADHD, healthcare providers and insurers consider MOA as a treatment choice, and creating the necessary collaborative bridge between mental health providers and dentistry.

To our knowledge, this is the first review to suggest the association of the reduction of ADHD symptoms with an oral appliance. Future studies are needed to evaluate the long-term benefits of therapy with an MOA, the correlation of the apnea-hypopnea index (AHI) and ADHD, factors that influence therapeutic success such as socioeconomic status, and create a screening tool that will initiate a clinical algorithm and interprofessional collaboration with another discipline in a non-medication treatment for ADHD.

Appendix

Sleep, Breathing & Habit Questionnaire

Patient's Name: ______________________________

Age: _______ Date: ________________

Please indicate if your child experiences any of the symptoms below by using this scale to measure the severity of these symptoms.

0—No Occurrence 1—Occurs Rarely 2—Occurs 2 to 4 times per week 3—Occurs 5 to 7 times per week

1. ______ Snoring
2. ______ Interrupted snoring where breathing stops
3. ______ Labored, difficult or loud breathing at night
4. ______ Gasping for air while sleeping
5. ______ Mouth breathes while sleeping
6. ______ Mouth breathes during the day
7. ______ Restless sleep
8. ______ Grinds teeth while sleeping
9. ______ Talks in sleep
10. ______ Excessive sweating while sleeping
11. ______ Wakes up at night
12. ______ Wets the bed (currently)
13. ______ History of bedwetting
14. ______ Feels sleepy and/or irritable during the day
15. ______ Headaches
16. ______ Frequent throat infections
17. ______ Allergic symptoms
18. ______ Ear infections
19. ______ Short attention span
20. ______ Trouble Focusing
21. ______ Difficulty listening often interrupts
22. ______ Hyperactive
23. ______ ADD/ADHD
24. ______ Sensory Issues
25. ______ Struggles in math at school
26. ______ Struggles in reading at school
27. ______ Speech problems *
28. ______ Avoidance behavior towards food or certain types of food

Speech Questionnaire—to be filled out only if #27 was indicated above

Author's Note

Statement of approval that all authors agree to and accept the manuscript for publication.

Author Contributions

Dr. Karen Parker Davidson, RN and Dr. Hamza Paracha had access to the data and takes responsibility for the accuracy of the analysis and integrity of the data. Contact david2k@cmich.edu. Concept and design: All authors. Acquisition, analysis, or interpretation of data: Corby Dixon, Zach Wilde. Drafting of the manuscript: All authors. Critical revision of the manuscript for important intellectual content: Davidson, Paracha. Statistical analysis: Dixon, Wilde. Administrative, technical, or material support: All authors. Additional Contributions: We thank Toshi Hart, DDS for her contributions.

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Clinical Trial

We do not declare this as a clinical trial.

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